K003237

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510(k) Summary of Safety and Effectiveness

Company: United Orthopedic Corporation
Address: No 57, Park Ave. 2, Science Park, Hsinchu, 300, Taiwan
Phone Number: 886-3-5773351
Fax Number: 886-3-5777156

Date Prepared: October 13, 2000.

Device Name: U2 Hip Stem, Ti porous coated (LPH)
Common Name: Cementless hip stem
Classification Name: Hip joint, Semi-Constrained, Metal/Polymer, Porous Uncemented Prosthesis per 21CFR 888.3358.
Predicate Device: Smith+Nephew Synergy Porous-Coated Stem (K991485)
DePuy AML Hip stem (K933787)
Encore Orthopedic Linear Porous Coated Hip Stem (K991325)

Device Description:

The UNITED U2 Ti porous coated stems are single use components. They are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. The U2 stems are manufactured from titanium alloy (ASTM F-620-97). The proximal area of stem is coated with two layers of porous coating using CP Ti powder (ASTM F1580-95). The U2 Ti porous coated hip stems have a 130° neck angle and Morse type taper to receive modular heads and are available in seven (7) sizes.

Intended Use:

The U2 hip stem is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoathritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed; and
5. Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Basis for Substantial Equivalence:

Endurance testing has been performed to demonstrate the substantial equivalence of this U2 Hip Stem, Ti Porous Coated, design to predicate stem designs in terms of its fatigue properties. And, the mechanical properties data indicates the U2 Hip Stem, Ti porous coated, is substantially equivalent to legally marketed devices.

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Address: No 57, Park Ave. 2, Science Park, Hsinchu, 300, Taiwan
Phone Number: 886-3-5773351
Fax Number: 886-3-5777156

Date Prepared: October 13, 2000.

Device Name: U2 Hip Stem, HA/Ti plasma spray (MEH)
Common Name: Cementless hip stem
Classification Name: Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate
Predicate Device: Secur-Fit™ HA Hip System (K982032)
TMZF® Press Fit HA Stem and TMZF® Press Fit Plus HA Stem (K994366)

Device Description:

The UNITED U2 HA/Ti plasma sprayed stems are single use components. They are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. The U2 stems are manufactured from titanium alloy (ASTM F-620). The proximal area of stem is plasma sprayed with dual materials, CP Ti powder (ASTM F67) coating plus Hydroxyapatite (HA, ASTM F1185) coating. The U2 hip stems have a 130° neck angle and Morse type taper to receive modular heads and are available in thirteen (13) sizes.

Intended Use:

The U2 hip stem is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoathritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed; and
5. Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Basis for Substantial Equivalence:

Features comparable to predicate devices include same materials, design and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2001

Ms. Mellen Liu
Regulatory Affairs
United Orthopedic Corporation
No. 57, Park Avenue
2, Science Park, Hsinchu
Taiwan, Republic of China

Re: K003237
Trade Name: U2 Hip Stem, Ti Porous Coated
Regulatory Class: II
Product Code: LPH

Trade Name: U2 Hip Stem, HA/Ti Plasma Sprayed
Regulatory Class: II
Product Code: MEH
Dated: October 13, 2000
Received: October 17, 2000

Dear Ms. Liu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K003237

Device Name: U2 Hip stem, Ti Porous Coated , U2 Hip stem, HA/Ti plasma sprayed

Indications for Use:

This device is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease such as osteoathritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Correction of function deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The Counter Use

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003237